UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

WAVE NEUROSCIENCE, INC. a Delaware Corporation,

Plaintiff,

vs.

BRAIN FREQUENCY LLC, a Texas Limited Liability Company

Defendant.

Case No. 5:23-CV-00626-XR

Honorable: Xavier Rodriguez

PLAINTIFF WAVE NEUROSCIENCE, INC.'S REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF OPPOSITION TO DEFENDANT BRAIN FREQUENCY, LLC'S MOTION FOR PARTIAL SUMMARY JUDGMENT PURSUANT TO THE PHYSICIAN'S IMMUNITY STATUTE

Pursuant to Fed. R. Evid. Rule 201, Plaintiff Wave Neuroscience, Inc. ("Wave") respectfully requests the Court take judicial notice of the documents identified herein with respect to the concurrently-filed Opposition to Defendant Brain Frequency, LLC's Motion for Partial Summary Judgment Pursuant to the Physician's Immunity Statute.

The Court may take judicial notice of facts that are not subject to reasonable dispute because those facts "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b)(2). "The doctrine of judicial notice permits a judge to consider a generally accepted or readily verified fact as proved without requiring evidence to establish it." *U.S. v. Berrojo*, 628 F.2d 368, 369 (5th Cir. 1980).

The below-referenced documents are publicly available on the U.S. Food and Drug Administration's website (510(k) Premarket Notification (fda.gov)), and are directly relevant to the issues at hand because they evidence the equipment Brain Frequency's software requires is approved by the FDA. As a result, they are properly judicially noticeable. *See Funk v. Stryker*

Corp., 631 F.3d 777, 783 (5th Cir. 2011) (holding it was appropriate for the court to take judicial notice of documents and transcripts produced by the FDA, where they are matters of public record and relevant to the issue at hand.); *see also Hyder v. Quarterman, No. CIV.A. C-07-291, 2007 WL 4300446, at *3 (S.D. Tex. Oct. 10, 2007)* (stating "[t]he Fifth Circuit has determined that courts may take judicial notice of governmental websites.")

1. 510(k) Summary regarding Number K230014, for the MagVenture Pain Therapy: MagPro R30, MagPro R30 with MagOption, MagPro X100,MagPro X100 with MagOption, a true and correct copy of which is attached hereto as **Exhibit A.**

2. 510(k) Summary regarding Number K193006, for the MagVenture TMS Therapy – for treatment of OCD, MagVenture TMS Therapysystem, a true and correct copy of which is attached hereto as **Exhibit B.**

3. 510(k) Summary regarding Number K171481, for the MagVita TMS Therapy System, a true and correct copy of which is attached hereto as **Exhibit C.**

4. 510(k) Summary regarding Number Number K170114, for the MagVita TMS Therapy System – w/MagPro R20, a true and correct copy of which is attached hereto as **Exhibit D.**

5. 510(k) Summary regarding Number K160280, for the MagPro R20, a true and correct copy of which is attached hereto as **Exhibit E.**

6. 510(k) Summary regarding Number K150641, for the MagVita TMS Therapy System, a true and correct copy of which is attached hereto as **Exhibit F.**

7. 510(k) Summary regarding Number K091940, for the MagPro, Models R30 With MagOption, X100, X100 With MagOption, a true and correct copy of which is attached hereto as **Exhibit G.**

8. 510(k) Summary regarding Number K061645, for the MagPro, Model R30, a true and correct copy of which is attached hereto as **Exhibit H.**

DATED: May 17, 2024

Respectfully submitted,

/s/ Deborah S. Mallgrave

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Attorneys for Plaintiff
WAVE NEUROSCIENCE, INC., a Delaware Corporation

EXHIBIT A

August 25, 2023

Tonica Elektronik A/S
Dr. Kirstine Schou
Medical Writer
MagVenture A/S
Lucernemarken 15
Farum, DK-3520
Denmark

Re: K230014
Trade/Device Name: MagVenture Pain Therapy: MagPro R30, MagPro R30 with MagOption, MagPro X100, MagPro X100 with MagOption,
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: QPL
Dated: August 8, 2023
Received: August 8, 2023

Dear Dr. Schou:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Amber T. Ballard -S

Amber Ballard, PhD
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230014

Device Name
MagVenture Pain Therapy: MagPro R30, MagPro R30 with MagOption, MagPro X100, MagPro X100 with MagOption

Indications for Use *(Describe)*
To stimulate peripheral nerves for relief of chronic intractable, post traumatic and post-surgical pain for patients 18 years or older

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

510(k) Number K230014

DATE PREPARED
08/25/2023

MANUFACTURER AND 510(k) OWNER
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REPRESENTATIVE
Kirstine Klitgaard Schou, Ph.D.
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DEVICE INFORMATION
Proprietary Name/Trade Name: MagVenture Pain Therapy: MagPro R30, MagPro R30 with MagOption, MagPro X100, MagPro X100 with MagOption

Common name:	Electromagnetic stimulator, pain relief
Regulation Number:	21 CFR 882.5890
Regulation Name:	Transcutaneous electrical nerve stimulator for pain relief
Class:	Class II
Product Code:	QPL
Review Panel:	Physical Medicine

PREDICATE DEVICE IDENTIFICATION
The *MagVenture Pain Therapy* (K230014) is substantially equivalent to the following predicate:

510(k) Number	Predicate Device Name / Manufacturer	Predicate
K210021	Axon Therapy/ NeuraLace Medical, Inc.	√

DEVICE DESCRIPTION

The *MagVenture Pain Therapy* is a magnetic stimulator system that provides brief and focused magnetic pulses in order to non-invasively stimulate peripheral nerves and provide relief of chronic intractable, post-traumatic and post-surgical pain. The subject device is intended to be used in hospitals and clinics such as pain management clinics. The device consists of Magnetic Stimulator, Stimulation Coils, Liquid Cool Unit (optional), and a Trolley. All coils of the *MagVenture Pain Therapy* have a built-in thermo sensor to measure the temperature of the coil surfaces to prevent high temperature on the skin of the patient or operator. The temperature allowed by the system is maximum 43°C or between 44ºC and 48ºC for less than 10 minutes. The system will automatically disable if this maximum temperature is reached.

INDICATIONS FOR USE

The *MagVenture Pain Therapy* is intended to stimulate peripheral nerves for relief of chronic intractable, post-traumatic and post-surgical pain for patients 18 years or older.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Tonica Elektronik A/S believes that the *MagVenture Pain Therapy* is substantially equivalent to the predicate device based on the information summarized here:

The subject device has a similar design and dimensions and uses similar or identical materials as the predicate device cleared in K210021. The subject device has identical technological characteristics to the MagPro Family cleared in K091940. These technological characteristics have undergone testing ensuring that the device is as safe and effective as the predicate.
While both the subject and predicate device are magnetic stimulators, with similar technological characteristics, and stimulation patterns, the subject device includes circular magnetic coils in addition to the butterfly geometry of the predicate device. Also, the devices differ in the ranges of pulse frequencies, maximum repetition rates, and maximum output power. As discussed below, these technological differences do not raise different questions of safety and effectiveness.

Tonica Elektronik A/S

Items	Subject device				Predicate device	Statement of equivalence
Trade Name	MagVenture Pain Therapy				Axon Therapy	Not applicable
Model Name	MagPro R30 (K091940)	MagPro R30 with MagOption (K091940)	MagPro X100 (K091940)	MagPro X100 with MagOption (K091940)		
510(k)	K230014				K210021	Not applicable
Manufacturer	Tonica Elektronik A/S				NeuraLace Medical, Inc.	Not applicable
Product codes/ Regulation Numbers	QPL (21 CFR 882.5890)				QPL (21 CFR 882.5890) IPF (21 CFR 890.5850)	Same
CLINICAL CHARACTERISTICS						
Indications for use	The MagVenture Pain Therapy is intended to stimulate peripheral nerves for relief of chronic intractable, post traumatic and post-surgical pain for patients 18 years or older.				The Axon Therapy is intended to stimulate peripheral nerves for relief of chronic intractable, post traumatic and post-surgical pain for patients 18 and older	Same
Anatomical sites	Any area, such as hand, arm,waist, buttock, thigh, calf, back and lower back etc.				Any area, such as hand, arm, chest, waist, buttock, thigh, calf, back and lower back etc.	Same
Treatment Facilities	Hospitals & Clinics				Hospitals & Clinics	Same
Treatment time	13 min per session (800 seconds)				13 min per session (800 seconds)	Same
TECHNOLOGICAL CHARACTERISTICS						
Pulse frequency	0.1-30 Hz (pps)	0.1-100 Hz (pps)			0-2 Hz (pps)	Substantially equivalent Refer to SE note 1
Pulse amplitude	0-100%				0-100%	Same

Tonica Elektronik A/S

On-cycle duty period	2-800 seconds (0.5 Hz and up to 400 pulses)				2-800 seconds (0.5 Hz and up to 400 pulses)	Same
Off-cycle reset period	N/A				N/A	Same
Maximum repetition rate	30 pulses per second		100 pulses per second		2 pulses per second (pps)	Substantially equivalent Refer to SE note 1
Pulse Width	Biphasic (280-320 µsec)				Biphasic (290 µsec)	Substantially equivalent
Pulse mode	Standard				Standard	Same
Maximum output power	100% at 15 pps				100% at 2 pps	Substantially equivalent Refer to SE note 2
Waveform	Biphasic	Biphasic, Monophasic	Biphasic, Biphasic Burst, Monophasic	Biphasic, Halfsine, Biphasic Burst, Monophasic	Biphasic	Substantially equivalent All devices are capable of biphasic mode
Maximum coil temperature	43°C				41°C	Same. The system will automatically disable if this maximum temperature is reached
Peak Magnetic Field at coil surface (T)	1.15-2.6 T*				Not publicly available	Substantially equivalent Refer to SE note 3
Peak Magnetic Field Gradient dB/dt in coil center at 20mm distance from the coil surface	9-24 kT/s*				Not publicly available	Substantially equivalent Refer to SE note 3
Software/Firmware/ Microprocessor control	Yes				Yes	Same
Power Source	Power Supply via Isolation Transformer Power Supply: 120V~, 50/60 Hz.				Power Supply: 110V to 220V ac, 50/60 Hz.	Same
	Power consumption: Maximum 2700VA				Power consumption: 800VA Maximum, 115W idle	
User Interface	LED display				LED display	Same

Housing Material Construction	Stimulator: Aluminum, Aluzinc Coils: PVC, ABS, PA, POM	Stimulator: Al sheet EN AW 5754 Coil: ABS	Substantially equivalent
Applied Parts	Magnetic coils: MMC-140-II (K061645) MCF-140 (K061645) RT-120-II (K061645) MMC-90 (K061645) MCF-125 (K071821) Cool-B65 (K071821) Cool-125 (K071821)	Magnetic coil 60BF-NL	Substantially equivalent Refer to SE note 3
Applied Parts area	Butterfly coils: 150 mm Circular coils:110-126 mm Special coils: 160×80 mm	160 mm	Substantially equivalent Refer to SE note 3
Sterilization	Non-sterile when used	Non-sterile when used	Same
PERFORMANCE DATA			
Electrical Safety	Complies with IEC60601-1 v3.1	Complies	Same
Mechanical Safety	Complies with IEC60601-1 v3.1	Complies	Same
Chemical Safety	Complies with IEC60601-1 v3.1	Complies	Same
Thermal Safety	Complies with IEC60601-1 v3.1	Complies	Same
Radiation Safety	No radiation generated	Complies	Same
Biocompatibility	Complies with ISO 10993	Complies	Same
Standards	Company complies with EN ISO 13485	Complies	Same

*No technological differences from K091940, but the definition of Peak Magnetic Field at coil surface changed. Likewise, the definition of Peak Magnetic Field Gradient at coil surface changed to lower values at a distance of 20mm from coil surface.

Substantial Equivalence Note 1

Comparison of subject and predicate pulse frequencies and maximum repetition rates.

The pulse frequencies of 0.1-30 Hz and 0.1-100 Hz and maximum repetition rates of 30 pps and 100 pps of the subject device are wider and higher, respectively, than the predicate device with pulse frequencies of 0-2 Hz and a maximum repetition rate of 2 pps. These differences do not raise different questions of safety and effectiveness since:

- The subject device can stimulate at 0.5 Hz the same as the predicate device.
- In the instructions for use, it is specified that the treatment parameter is 0.5 Hz.

- The maximum repetition rates of 30 and 100 Hz are both within the range of physiological action potentials (from 0.05 to 500 Hz) of the human nervous system and thus pose no new risk to the patients.

- The subject device is substantially equivalent to the predicate device for the following treatment protocol as outlined in the instructions for use. Treatment parameters (e.g., repetition rate, pulses per train, number of trains, number of pulses, inter train interval, treatment time) that are not included in the treatment protocol have not been evaluated for effectiveness in the relief of chronic intractable, post traumatic and post-surgical pain for patients 18 years or older.

  TREATMENT PROTOCOL

  Three to four treatments over two months and maintenance therapy every 6 to 8 weeks is recommended.

Treatment level:	Individually estimated (% of maximum output power)
Repetition rate:	0.5 pps
Pulses per train:	10
Number of trains:	40
Number of pulses:	400
Inter train interval:	2 s
Treatment time:	13 min

In conclusion, higher ranges of pulse frequencies and higher maximum repetition rates do not raise any new or different questions of safety and effectiveness.

Substantial Equivalence Note 2
Comparison of subject and predicate maximum output power.

The maximum output power of the subject device is 100% in the range of 0.1 to 15 pps while the predicate device is 100% in the range of 0.5 to 2 pps. Consequently, at 2 pps the subject device and the predicate device are both able to obtain a maximum output of 100% signifying they are equally effective.

In conclusion, since both devices perform 100% at 2 pps there are no new issues of safety and effectiveness. The difference in maximum output power does not raise new or different questions of safety and effectiveness.

Substantial Equivalence Note 3
Comparison of Subject and Predicate Magnetic Coils

The subject device has both circular and butterfly coils while the predicate only has a butterfly coil. However, all the coils are basically constructed the same way: A cobber winding element encapsulated in a plastic housing.
The size of the magnetic field depends on the diameter and number of windings. The number of windings only varies slightly and the diameters of the subject device coils are close to the predicate coil.

Except for minor differences in geometry, the butterfly coils of the predicate and subject devices are similar. In comparison to the butterfly geometry, the circular coils have just one coil element. This gives a better usability with no rotation limitation. *All coils achieve the same intended use.* The differences in the electric field and spatial characteristics (maximum magnetic fields at the coil surface (T) and the magnetic gradients (dB/dt)) of the circular and butterfly geometries are negligible and have no documented impact on effectiveness or safety of the intended use.

It is concluded that the differences in coil geometry do not raise new or different questions of safety and effectiveness.

SUMMARY OF NON-CLINICAL TESTING

The subject device is identical to the MagPro Family device (K094019) in all features (e.g., design, dimensions, materials, biocompatibility), except for the indications for use. Therefore, no new bench testing is needed.

DISCUSSION

The subject device has the same intended use, indications for use, and similar technological characteristics, and principles of operation as the predicate device. Also, the target population, the dosage, the treatment procedure, and all specific protocol parameters (intensity, repetition rate, number of pulses) are identical for the subject and the predicate device.

The subject device has a broader range of pulse frequencies and higher maximum repetition rates compared to the predicate device. Still, both devices are able to run the stimulation protocol of 400 pulses at 0.5 Hz. Furthermore, the maximum repetition rates of the predicate device are all within the range of physiological action potentials of the human nervous system and thus pose no new risk to the patients. The maximum output power of the subject device is higher than the predicate devices. Nevertheless, both devices perform 100% at 2 pps signifying they are equally effective. The subject device is substantially equivalent to the predicate device for the treatment protocol as described above. Treatment parameters (e.g., repetition rate, pulses per train, number of trains, number of pulses, inter train interval, treatment time) that are not included in the treatment protocol above have not been evaluated for effectiveness in the relief of chronic intractable, post traumatic and post-surgical pain for patients 18 years or older.

Finally, the subject device has both circular and butterfly coils while the predicate only has a butterfly coil. However, all the coils are basically constructed the same way: a cobber winding element encapsulated in a plastic housing. Except for minor differences in geometry, the butterfly coils of the predicate and subject devices are similar. In comparison to the butterfly geometry, the circular coils have just one coil element. This gives a better usability with no rotation limitation. All coils achieve the same intended use. The differences of the circular and butterfly geometries are negligible and do not raise new or different questions of safety and effectiveness.

CONCLUSION

Except for the indication for use, the subject device is identical to the previously cleared MagPro family device. Thus, software validation, electrical safety testing, and performance testing can be leveraged for this device. The similar indications for use, stimulation patterns, technological characteristics, and performance characteristics for the proposed *MagVenture Pain Therapy* are assessed to be substantially equivalent to the predicate device.

EXHIBIT B

August 9, 2020

Tonica Elektronik A/S
Sanne Jessen
Medical Advisor, MSc, PhD
Lucernemarken 15
DK-3520 Farum, Denmark

Re: K193006
Trade/Device Name: MagVenture TMS Therapy - for adjunctive treatment of OCD, MagVenture TMS Therapy system
Regulation Number: 21 CFR 882.5802
Regulation Name: Transcranial Magnetic Stimulation System For Neurological And Psychiatric Disorders And Conditions
Regulatory Class: Class II
Product Code: QCI
Dated: April 29, 2020
Received: May 6, 2020

Dear Sanne Jessen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

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Sincerely,

Pamela D. Scott -S

Pamela Scott
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193006

Device Name
MagVenture TMS Therapy System

Indications for Use *(Describe)*
The MagVenture TMS Therapy System is intended to be used as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Submitter's Information

Name of 510(k) owner: Tonica Elektronik A/S
Lucernemarken 15
DK-3520 Farum, Denmark
Phone/ Fax: +45 4499 8444 / +45 4499 1544

Contact person: Sanne Barsballe Jessen
Medical Advisor
Email: sj@magventure.com
Office: +453840 8449
Cell: +45 3119 9516

Other:
Jan Kjoeller
Email: jk@tonica.dk

Preparation date: August 8, 2020

Trade names: MagVenture TMS Therapy system
MagVenture TMS Therapy system – for adjunctive treatment of OCD

Common name: Transcranial Magnetic Stimulator

Classification name: Transcranial Magnetic Stimulation System for Neurological and Psychiatric Disorders and Conditions [21 CFR 882.5802] [Product Code QCI - Transcranial Magnetic Stimulation System for Obsessive-Compulsive Disorder]

Classification:
Class II Medical Device

Predicate Devices:

Primary Predicate
Brainsway Deep Transcranial Magnetic Stimulation (DTMS) system, HAC – H7 coil (DEN170078, K183303)
21 CFR 882.5802, Transcranial Magnetic Stimulation System for Neurological and Psychiatric Disorders and Conditions
Product Code: QCI - Transcranial Magnetic Stimulation System for Obsessive-Compulsive Disorder

510(k)

MagVenture TMS Therapy system – for adjunctive treatment of OCD

Class II

Predicates

MagVenture TMS Therapy system (K150641, K171481, K171967, K172667, K173620)
21 CFR 882.5805, Repetitive Transcranial Magnetic Stimulation
Product code: OBP
Device Class: II

Device description

The MagVenture TMS Therapy system - for adjunctive treatment of OCD is a computerized, electromechanical medical device that produces and delivers non-invasive, magnetic fields to induce electrical currents targeting specific regions of the cerebral cortex. The MagVenture TMS Therapy system - for treatment of OCD is indicated as an adjunct for the treatment of adult patients who are suffering from Obsessive-Compulsive Disorder (OCD). MagVenture TMS Therapy system has previously obtained FDA clearance for treatment of major depressive disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode (K150641, K171481, K171967, K172667, K173620).

Transcranial magnetic stimulation (TMS) is a non-invasive technique for stimulating brain and neural tissue. The principle of magnetic stimulation is implicit in Faraday's law. The pulses of current are generated with a circuit containing a capacitor connected to the stimulating coil. With the capacitor charged to a certain level, the conducting state will cause the discharging of the capacitor through the coil. A magnetic field is generated proportional to this current. The rapid change in the magnetic field induces a current in conducting materials e.g. the body tissue. If the current induced in the human body is of sufficient amplitude and duration, it will excite neurons. The standard-of-care FDA cleared TMS protocol for treatment of OCD uses repetitive transcranial magnetic pulses applied at a frequency of 20 Hz. The safety and effectiveness for treatment of OCD have been established in a clinical trial that lead to an FDA De Novo clearance of the primary predicate device, the Brainsway DTMS system. The present 510(k) does not include new pivotal data, but includes clinical trial data on more than 500 subjects treated with the MagVenture TMS Therapy System, in order to demonstrate performance and safety. Treatment of OCD is applied to the human brain of the bilateral dorsomedial prefrontal cortex (DMPFC) using 20 Hz TMS for 18 min. The treatment parameters are identical to those recommended by the Primary Predicate Device.

510(k)

MagVenture TMS Therapy system – for adjunctive treatment of OCD

The MagVenture TMS Therapy system – for adjunctive treatment of OCD is an integrated system consisting of the following components:

- MagPro Stimulator and Trolley
  - MagPro Family (R30, R30 w. MagOption, X100, X100 w. MagOption)
  - Trolley with holding arrangements
- Coil for MT determination and OCD treatment
  - Coil Cool D-B80 with Coil Cooler Unit
- Marking apparatus for locating treatment area
  - Pen for marking, Cap, Ruler
- Patient head fixation
  - Treatment Chair
  - Vacuum Pump and Vacuum pillow
  - Super Flexible Arm mounted on the trolley
- Isolation Transformer

Intended Use

The MagVenture TMS Therapy system is intended to be used as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD).

The intended use is identical to that of the Primary Predicate Device.

Performance Standards:

The MagVenture TMS Therapy system - for adjunctive treatment of OCD has been tested and conforms with the following standards

- ISO 13485:2016
- IEC60601-1
- IEC60601-1-2

Non-Clinical performance data:

The contents of this 510(k) complies with the FDA Guidance Document: “Class II Special Controls Guidance Document: Repetitive Transcranial Magnetic Stimulation (rTMS) Systems - Guidance for Industry and Food and Drug Administration Staff”.
The non-clinical performance testing of the components of the MagVenture TMS Therapy system - for treatment of OCD has been tested as required according to the standards listed above. All components, except the Cool D-B80 coil, have previously been cleared by the FDA, see K150641, K171481, K172667 and K173620.
The MagVenture TMS Therapy system – for adjunctive treatment of OCD consists of components that are identical to those of the predicate device, with the exception of the Cool D-B80 coil. The new coil is identical to the predicate device in terms of biocompatibility, design elements, such as cable lengths, coil materials, cooling media,

isolation design and functionalities. All coils are subject to high-voltage tests and leakage current tests to ensure safety.
To establish substantial equivalency for the new coil, Cool D-B80, and the primary predicate device, especially the HAC – H7 coil, we have performed substantial equivalence comparisons for testing and performance as described in Section 4 of the FDA's Class II Special Controls Guidance document: Repetitive Transcranial Magnetic Stimulation (rTMS) Systems.
We have performed a comparative testing of the magnetic field distribution for the Cool D-B80 coil and compared to that of the primary predicate device. This comparison determines that the magnetic spatial distribution is substantially equivalent. Both coils are so-called double cone coils, containing two coils that do not overlap, and allows for a deeper and broader stimulation of the cortex. We have provided information about magnetic field characteristics, including linearity of output level, magnetic field strength gradients, output waveform and magnetic field spatial distribution according to the Special Controls Guidance document, Section 4 as mentioned above. In addition, we have provided magnetic field characteristics for other, different relevant clinical depths of the human brain than those specified in the Special Controls Guidance and in the De Novo Summary of the Primary Predicate Device, which limits information to 2 cm depth.

In addition, we have modelled the magnetic properties of the New Device and the Primary Predicate Device, the HAC-7 coil. Our coil model calculations are based on the concept of well-established scientific methods (1).
The results of the e-field modelling of the HAC-7 coil is in line with the Manufacturer information provided in the De Novo Summary for the primary predicate device, DEN170078. The results of the e-field model show the magnetic field strength in the cortex for the two coils. This shows that the Cool D-B80 coil is able to reach the deeper underlying cortical layers similarly to the HAC – H7 coil. Based on the modelling, it is therefore concluded, that the magnetic field properties of the Cool D-B80 coil is substantially equivalent to the primary predicate device, HAC – H7 in terms of magnetic field properties and realized magnetic field properties. The modelling was used to support the technological comparison provided.

We have also provided information about the magnetic field spatial distribution of the new coil superimposed on T1-weighted MRI coronal, sagittal, and axial 1 cm slices. These images support the substantial equivalence comparisons determination and together with the above information, further supports the substantial equivalence of the new device compared to the primary predicate device, HAC-7.

We have also tested the new device according to IEC60601 3rd edition and verified that the device complies with the specified permissible sound pressure levels. The device also

complies with the permissible thresholds for exposure defined by the Occupational Safety and Health Administration (OSHA).
These tests provide evidence that the MagVenture TMS Therapy system does not pose any risk for potential hearing reduction or loss in either patients or operators.

Clinical performance data:

This 510(k) does not contain any pivotal clinical trial data related to the new device. The substantial equivalency was established based on similar technological characteristics, but we have provided some clinical trial data to support the safety of the new device. The clinical evidence submitted also supports the safety and use of the new device as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD).
A number of clinically relevant scientific references including more than 500 subjects treated with MagVenture TMS Therapy using the Cool D-B80 coil have been included with full text, as well as a summary and rationale for how these references support SE determination and/or safety and effectiveness for the new device for the proposed indication for use and for the proposed treatment protocol.

The primary predicate device De Novo Summary refers to a publication by Carmi et al. (2), who published the results of their pivotal trial supporting the De Novo, DEN170078. This study included a total of n=99, of which n= 50 received active TMS treatment. The proposed indication for use and treatment protocol are identical to that of the primary predicate device.

The new device is already cleared for use in both Europe and Canada and has been used in clinical research for a number of years.
Most of the clinical research performed using the new device has been conducted outside the USA. Most research has focused on the use of the new device for treatment of treatment-resistant depression (TRD) or major depressive disorder (MDD). There has been considerable interest in investigating the DMPFC as a target for TRD/MDD. Though MDD/TRD and OCD are distinct psychiatric disorders they share common underlying deficits in cortical networks. Thus, it is therefore relevant to demonstrate that the new device can be used to deliver TMS at the right treatment location, DMPFC, and that this can lead to modulation of deeper brain structures and long-range networks that are important in the recovery of symptoms of OCD as well as MDD. In addition, the clinical trials also demonstrate that the new device can be used efficiently and routinely to determine MT in the leg or foot, in a substantially equivalent way to the primary predicate device. Importantly, the clinical data also helps demonstrate safety for the new device.

In summary, the literature referenced includes a total of 521 subjects treated with TMS or iTBS protocols effectively targeting the DMPFC using the new device with treatment intensity defined based on the use of Leg MT. It is noteworthy that most of the clinical investigations have utilized treatment intensities that are higher than those used by the primary predicate device for OCD as reported by Carmi et al (2). Thus, treatment with the new device at an intensity of 100% Leg MT might be even more tolerable and safer in comparison with higher intensity. Despite this difference in intensity, the clinical data for the new device shows that the treatment overall is well-tolerated and safe. The treatment with the new device does not introduce any new adverse or serious adverse events. In fact, the side effect profile resembles that of standard TMS and iTBS treatment of the L-DLPFC and it is also equivalent to the side effect profile of the primary predicate device.
We therefore conclude that the treatment with the new device is safe and provides equivalent performance to the primary predicate device in terms of safety and performance. The most common side effects reported for both devices are headache and/or pain at stimulation site.
In addition, a small pilot trial using the new device also demonstrated a clinically and statistically significant effect of treatment of OCD. Despite the low number of subjects, this trial supports the performance of the new device as an adjunct for treatment of OCD, even though the protocol was utilizing lower frequency of stimulation, that is 10 Hz compared to 20 Hz.

Taken together, the literature demonstrates that the new device can be used effectively and routinely for determining Leg MT, and that the treatment modulates brain activity locally in the DMPFC and strongly suggests also distal brain areas, through downstream activation of long-range networks. Though MDD and OCD are two distinct psychiatric disorders, they share some common underlying deficits in brain networks. So, though most of the research using the new device has investigated treatment of MDD, the data can support the use of the new device as an adjunct for treatment of OCD in terms of safety and given that the treatments have been performed targeting the same cortical area, DMPFC bilaterally, in a substantially equivalent way to the primary predicate device.

Finally, the clinical data for the new device essentially supports the modelled e-fields presented above, and treatment with the new device is as safe as treatment with the primary predicate device. There is no reason to suspect increased risk for unwanted or severe side effects. Moreover, clinical data shows the new device’s ability to deliver effective treatment of the DMPFC and potentially affecting deeper cortical brain areas. We therefore conclude that the new device is substantially equivalent to the primary predicate device in terms of performance, effectiveness and safety.

Substantial equivalence:
The MagVenture TMS Therapy system - for adjunctive treatment of OCD is substantially equivalent to the primary predicate device, the Brainsway DTMS system HAC – H7 coil. The MagVenture TMS Therapy system - for treatment of OCD and the primary predicate device have identical indication for use, and identical treatment parameters as well as treatment target. The magnetic field properties of the Cool D-B80 is substantially equivalent to the primary predicate device, the Brainsway DTMS HAC – H7 coil (DEN170078, K183303).
All components of the new device, except the Cool D-B80 coil, are identical to those of the predicate device. These have all previously obtained FDA clearance for treatment of major depressive disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode (K150641, K171967 and K173620).
The new coil, Cool D-B80 is also identical to that of the predicate devices, in terms of materials, design elements, liquid cooling and biocompatibility.

The treatment protocol is identical to that of the primary predicate device, and applies transcranial magnetic stimulation (TMS) at an intensity of 100% of Leg Motor Threshold (MT) as repetitive pulse trains at a frequency of 20 Hz delivered as brief rapidly alternating magnetic fields to induce electrical currents over the dorsomedial prefrontal cortex (DMPFC). All labelling claims related to effectiveness and safety are based on the literature describing the pivotal clinical trial results of the primary predicate device for the proposed intended use.
Both the MagVenture TMS Therapy system - for adjunctive treatment of OCD and the predicate devices consist of the same components, that is a TMS stimulator with software, an articulated arm for positioning of the treatment coil. The operational procedures including system setup, patient preparations, motor threshold determination and coil positioning are substantially equivalent.

510(k)

MagVenture TMS Therapy system – for adjunctive treatment of OCD

Area	New Device	Predicate Device	Primary Predicate Device
	MagVenture TMS Therapy system – for treatment of OCD **Tonica Elektronik A/S, Denmark**	**MagVenture TMS Therapy system** **(K150641, K171481, K171967, K172667, K173620)** **Tonica Elektronik A/S, Denmark**	**Brainsway Deep Transcranial magnetic stimulation (DTMS) System and HAC – H7 coil (DEN170078, K183303)** **Brainsway Ltd., Israel**
Indications for use	The MagVenture TMS Therapy System is intended to be used as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD)	NA	The Brainsway DTMS system is intended to be used as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD)
Energy Delivered and Performance	<u>Treatment parameters:</u> Intensity: 100% of Leg MT (Leg Motor Threshold) Repetition rate: 20Hz Train duration: 2 sec Inter-train-Interval: 20 secs Number of trains: 50 Numbers of pulses: 2000 Total duration: 18.0 min.	NA	<u>Treatment parameters:</u> Intensity: 100% of Leg MT (Leg Motor Threshold) Repetition rate: 20Hz Train duration: 2 sec Inter-train-Interval: 20 secs Number of trains: 50 Numbers of pulses: 2000 Total duration: 18.3 min.
	<u>Treatment area:</u> Area of brain to be stimulated: Dorsomedial Prefrontal Cortex	NA	<u>Treatment area:</u> Area of brain to be stimulated: Dorsomedial Prefrontal Cortex
	<u>Output Stimulation Parameters:</u> Available Stimulation Intensity in terms of Standard Motor Threshold (SMT) units Range: 0 - 1.9 SMT Waveform: Biphasic	<u>Output Stimulation Parameters:</u> Available Stimulation Intensity in terms of Standard Motor Threshold (SMT) units Range: 0 - 1.7 SMT Waveform: Biphasic	<u>Output Stimulation Parameters:</u> Available Stimulation Intensity in terms of Standard Motor Threshold (SMT) units Range: 0.6- 1.4 SMT Waveform: Biphasic
Design	<u>The system consists of</u>: 1. Mobile console 2. System software with GUI 3. Treatment chair* 4. Head support system* 5. Coil positioning system 6. Same Coil for both MT and treatment 7. Coil Fixture 8. Data Management System **optional*	<u>The system consists of</u>: 1. Mobile console 2. System software with GUI 3. Treatment chair* 4. Head support system* 5. Coil positioning system 6. Coil for MT and coil for treatment 7. Coil Fixture 8. Data Management System **optional*	<u>The system consists of</u>: 1. Mobile console 2. System software 3. Treatment chair* 4. Helmet with Coil for MT 5. and for treatment 6. Coil positioning system
Coil	Double-cone coil Air core	Figure-of-eight coils (butterfly coil) Air core	Double-cone coil contained in a helmet. Air core

Cooling	Liquid cooled Used for both MT determination and treatment.	Liquid cooled Used for both MT determination and treatment.	Air cooled. Used for both MT determination and treatment.
Standards	Company complies with EN ISO 13485:2016.	Company complies with EN ISO 13485:2016.	Company complies with ISO 13485:2016.
Electrical safety	Complies with IEC60601-1 v. 3.1, and IEC60601-1-2.	Complies with IEC60601-1 v. 3.1, and IEC60601-1-2.	

For a more comprehensive comparison of devices please refer to section 10, Device Description and section 12, Substantial Equivalence Comparison.

Conclusion:

The new device, MagVenture TMS Therapy system – for adjunctive treatment of OCD, is identical to the predicate device, MagVenture TMS Therapy system, except for the treatment coil, Cool D-B80, which has not previously been cleared by the FDA. All other components of the new device have previously been cleared by the FDA, most recently in 2018 (K173620).

The indication for use, the target population, the TMS treatment protocol and the treatment position are all identical for the MagVenture TMS Therapy system and the primary predicate device, Brainsway DTMS System (DEN170078). The treatment parameters proposed for the new device are identical to those recommended by the primary predicate device. Clinical evidence pertaining to the new device demonstrates that the treatment is safe, well-tolerated and effective. The new device is substantially equivalent to the primary predicate device in terms of performance, safety and effectiveness.

The new coil is identical to the predicate coils, Cool-B70 and Cool-B65, in terms of design parameters, such as materials, biocompatibility, liquid cooling and pulse width. The new coil is substantially equivalent to the primary predicate device, Brainsway DTMS HAC – H7 coil in terms of magnetic properties and magnetic spatial distribution. The two coils are both so-called double cone coils, which contain two individual, non-overlapping magnetic coils that allow for a broader and more deep stimulation of the cortex. E-field modelling of the new device compared to the primary predicate device demonstrates that the magnetic field properties and the depth penetration of the two devices in the human cortex are substantially equivalent.
The clinical data submitted with this 510(k), helps support the performance and safety of the new device and shows that also the side effect profile is substantially equivalent to that of the primary predicate.

The reliability of the positioning method used by the new device is based on the direct relationship of the underlying cortical brain anatomy to the patient's scalp, identical to the method used for the predicate devices.

The MagVenture TMS Therapy system – for adjunctive treatment of OCD does not introduce any new safety considerations in comparison to the predicate devices.

All other identified differences between the two systems are minor and without any impact on safety or efficacy.

The above comparison demonstrates and supports the substantial equivalence of the MagVenture TMS Therapy system – for adjunctive treatment of OCD to the predicate devices, Brainsway DTMS System (DEN170078; primary predicate), and the MagVenture TMS Therapy system (K150641, K171481, K171967, K172667, K173620).

Reference List

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3. Dunlop K, Woodside B, Olmsted M, Colton P, Giacobbe P, Downar J. Reductions in Cortico-Striatal Hyperconnectivity Accompany Successful Treatment of Obsessive-Compulsive Disorder with Dorsomedial Prefrontal rTMS. Neuropsychopharmacology. 2016;41(5):1395-403.

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10. Bakker N, Shahab S, Giacobbe P, Blumberger DM, Daskalakis ZJ, Kennedy SH, et al. rTMS of the dorsomedial prefrontal cortex for major depression: safety, tolerability, effectiveness, and outcome predictors for 10 Hz versus intermittent theta-burst stimulation. Brain Stimul. 2015;8(2):208-15.

EXHIBIT C

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 16, 2017

Tonica Elektronik A/S
Lise Terkelsen
QA/RA Manager
Lucernemarken 15
Farum, 3520 Dk

Re: K171481
Trade/Device Name: MagVita TMS Therapy System
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive transcranial magnetic stimulation system
Regulatory Class: Class II
Product Code: OBP
Dated: May 17, 2017
Received: May 19, 2017

Dear Lise Terkelsen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

William J. Heetderks -S
2017.06.16 12:07:00 -04'00'

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171481

Device Name
MagVita TMS Therapy System

Indications for Use *(Describe)*
The MagVita TMS Therapy System is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to recieve satisfactory improvement from prior antidepressant medication in the current episode

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Special

MagVita TMS Therapy System

510(k) Summary

Submitter's Information

Name of 510(k) owner:	Tonica Elektronik A/S Lucernemarken 15 DK-3520 Farum, Denmark
Phone:	+45 4499 8444
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Contact person:	Lise Terkelsen Email: lise.terkelsen@tonica.dk

Preparation date:	May 15, 2017
Trade name:	MagVita TMS Therapy System
Common name:	Transcranial Magnetic Stimulator
Classification name:	Repetitive Transcranial Magnetic Stimulator for treatment of Major Depressive Disorder [21 CFR 882.5805, Product Code OBP]
Classification:	Class II Medical Device
Predicate Devices:	Neurostar TMS Therapy System, K160703 MagVita TMS Therapy System, K150641
Special Controls:	The 510k submission addressed the special controls required by regulation and specified in the FDA guidance document titled "Class II Special Controls Guidance Document: Repetitive Transcranial Magnetic Stimulation (rTMS) Systems

MagVita TMS Therapy System

Device description

The MagVita TMS Therapy System is a computerized, electromechanical medical device that produces and delivers non-invasive, magnetic fields to induce electrical currents directed at regions of the cerebral cortex. The MagVita TMS Therapy System is indicated for

Treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode

Transcranial magnetic stimulation (TMS) is a non-invasive technique for stimulating brain and neural tissue. The principle of magnetic stimulation is implicit in Faraday's law. The pulses of current are generated with a circuit containing a capacitor connected to the stimulating coil. With the capacitor charged to a certain level, the conducting state will cause the discharging of the capacitor through the coil. A magnetic field is generated proportional to this current. The rapid change in the magnetic field induces a current in conducting materials e.g. the body tissue. If the current induced in the human body is of sufficient amplitude and duration, it will excite neurons.

In the MagVita TMS therapy system TMS pulses are applied repetitively at a frequency of 10Hz. Such stimulation has been shown to be effective in modulating cortical excitability. The observed and documented increase in cortical excitability after high frequency (10Hz) repetitive transcranial magnetic stimulation has been shown to persist beyond the duration of the train of stimulation. Repetitive Magnetic stimulation with the MagVita TMS therapy system is applied to the human brain on the left dorsolateral prefrontal cortex (DLPFC).

- MagPro Stimulator and Trolley
  - MagPro family
  - Trolley with holding arrangements
- Coil for MT determination
  - Coil C-B60
- Marking apparatus for locating treatment area
  - Marking plate for Coil C-B60
  - Pen for marking, Cap, Ruler
- Patient head fixation
  - Treatment Chair
  - Vacuum Pump and Vacuum pillow
  - Super Flexible Arm mounted on the trolley
- Coil for Depression Treatment
  - Coil Cool-B65 with Coil Cooler unit
- Isolation Transformer

MagVita TMS Therapy System

Intended Use/Indication for Use:

Treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.

Standards:
The MagVita TMS Therapy System has been tested and complies with the following standards

- ISO 13485:2012
- IEC60601-1
- IEC60601-1-1
- IEC60601-1-2

Non-Clinical performance data:

The non-clinical performance testing of the components of the MagVita TMS Therapy System has been tested as required, and cleared by the FDA earlier on K091940 and K150641.

These tests demonstrate that the MagVita TMS Therapy System is safe and effective for use in treatment of Major Depressive Disorder.

Substantial equivalence:

The MagVita TMS Therapy System is substantially equivalent to the predicate devices (our own MagVita TMS Therapy System and Neurostar TMS). The MagVita TMS Therapy System and the predicate devices have identical intended use /indication for use, and technological characteristics. The principles of operation, the output stimulation parameters and the materials are equivalent to the predicates. The modification to the device allows a range of inter-train intervals from 11 to 26 seconds, rather than the fixed 26 second duration, which will allow a reduction in treatment time from 37.5 minutes to a minimum of 18.8 minutes.

The MagVita TMS Therapy System and the predicate devices are all indicated for

Treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.

Design of the MagVita TMS Therapy System is similar to the predicate device as both systems apply Transcranial Magnetic Stimulation as repetitive pulse trains at 10Hz delivered as brief rapidly alternating magnetic fields to induce electrical currents over the prefrontal cortex.
Both the MagVita TMS Therapy System and the predicate devices have the same components consisting of TMS stimulator with software, electromagnetic coil and an articulated arm for positioning of the treatment coil. The operational procedures including system setup, patient preparations, motor threshold determination, coil

positioning and treatment with predefined treatment stimulation parameters are essentially the same.

Characteristics of the Device as Compared to Predicate Devices

Criteria	MagVita TMS Therapy System	MagVita TMS Therapy System (K150641)	NeuroStar TMS Therapy System (K160703)
Performance	Waveforms: Biphasic. Frequency: 0.1 -30 pulses per second or 0.1 -100 pulses, depending on model	Waveforms: Biphasic. Frequency: 0.1 -30 pulses per second or 0.1 -100 pulses, depending on model	Waveforms: Biphasic Frequency: 0.1 -30 pulses per second.
	Recommended standard treatment: Stimulation Intensity: 120% MT Repetition rate:10 Hz Train duration: 4 sec Inter-train interval: 11-26 sec Pulses/session: 3000 Treatment duration: 18.8 min.	Recommended standard treatment: Stimulation Intensity: 120% MT Repetition rate: 10 Hz Train duration: 4 sec Inter-train interval: 26 sec Pulses/session: 3000 Treatment duration: 37 min.	Recommended standard treatment: Stimulation Intensity: 120% MT Repetition rate: 10 Hz Train duration: 4 sec Inter-train interval: 11-26 sec Pulses/session: 3000 Treatment duration: 18.8 min.
	Output Stimulation Parameters: Amplitude in Standard Motor Threshold (SMT) units : 0 – 1.7 Pulse width: 290 µs, Biphasic sinusoid waveform. Frequency Range: 0.1-30 pps or 0.1-100 pps, depending on model	Output Stimulation Parameters: Amplitude in Standard Motor Threshold (SMT) units: 0 - 1.7 Pulse width: 290 µs, Biphasic sinusoid waveform. Frequency Range: 0.1-30 pps or 0.1-100 pps, depending on model	Output Stimulation Parameters: Amplitude in Standard Motor Threshold (SMT) units: 0.22 - 1.6 Pulse width: 185 µs (±10%), Biphasic sinusoid waveform.. Frequency Range: 0.1-30 pps
Coil Configuration Cooling	Figure-of-eight coil Air core Liquid cooling	Figure-of-eight coil Air core Liquid cooling	Figure-of-eight coil Ferromagnetic core Ferrofluidic cooling
Standards met	Company complies with ISO 13485:2012.	Company complies with ISO 13485:2012	Company complies with ISO 13485:2003
Electrical safety	Complies with IEC60601-1 3rd edition, and IEC60601-1-2.	Complies with IEC60601-1 3rd edition, and IEC60601-1-2.	Complies with IEC60601-1 and IEC60601-1-2.

Conclusion:

The above comparison, demonstrates and supports the substantial equivalency of the *MagVita TMS Therapy System* to our own *MagVita TMS Therapy System* and the *NeuroStar TMS Therapy System.*

The indication for use, the target population, the dosage, the treatment procedure, the treatment position and all relevant protocol parameters (intensity, repetition rate, number of pulses in a train, numbers of trains, number of treatment sessions) are identical for the *MagVita TMS Therapy System* and the predicate devices.

The transducer design (figure-of-eight) are equivalent and the realized magnetic properties of the *MagVita TMS Therapy System* and the predicate devices are substantial equivalent.

The reliability of the positioning method used by the *MagVita TMS Therapy System* is, based on the direct relationship of the underlying cortical brain anatomy to the patient's scalp, as is the method used in the predicate devices. The method for identifying the correct treatment position in the MagVita TMS Therapy System is at least as effective as the method employed by the predicate devices.

On the basis of the only modification of the treatment parameter, the *MagVita TMS Therapy System* does not introduce any new safety considerations in comparison to the predicate devices

All other identified differences between the three systems are minor and without impact on safety or efficacy.

EXHIBIT D

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 1, 2017

Tonica Elektronik A/S
Lise Terkelsen
Regulatory Affairs / Quality Assurance Specialist
Lucernemarken 15
Farum, DK-3520 DK

Re: K170114
Trade/Device Name: Magvita TMS Therapy - W/MagPro R20
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive Transcranial Magnetic Stimulation System
Regulatory Class: Class II
Product Code: OBP
Dated: March 31, 2017
Received: April 3, 2017

Dear Lise Terkelsen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

William J. Heetderks -S

Digitally signed by William J. Heetderks -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=0010149848, cn=William J. Heetderks -S
Date: 2017.05.01 13:08:06 -04'00'

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170114

Device Name
MagVita TMS Therapy System with MagPro R20

Indications for Use *(Describe)*
The MagVita TMS Therapy – w/MagPro R20 is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Submitter's Information

Name of 510(k) owner: Tonica Elektronik A/S
Lucernemarken 15
DK-3520 Farum, Denmark
Phone: +45 4499 8444
Fax: +45 4499 1544

Contact person: Lise Terkelsen
Email: lise.terkelsen@tonica.dk

Preparation date: January 9, 2017

Trade name: MagVita TMS Therapy w/MagPro R20

Common name: Transcranial Magnetic Stimulator

Classification name: Repetitive Transcranial Magnetic Stimulator for treatment of Major Depressive Disorder [21 CFR 882.5805, Product Code OBP]

Classification: Class II Medical Device

Predicate Device: MagVita TMS Therapy System (K150641)
21 CFR 882.5805, Repetitive Transcranial Magnetic Stimulation
Product code: OBP
Device Class: II

Special Controls: The 510k submission addressed the special controls required by regulation and specified in the FDA guidance document titled "Class II Special Controls Guidance
Document: Repetitive Transcranial Magnetic Stimulation (rTMS) Systems

510(k)

MagVita TMS Therapy w/MagPro R20

Device description

The MagVita TMS Therapy w/MagPro R20 is a computerized, electromechanical medical device that produces and delivers non-invasive, magnetic fields to induce electrical currents directed at regions of the cerebral cortex. The MagVita TMS Therapy w/MagPro R20 is indicated for

Treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.

Transcranial magnetic stimulation (TMS) is a non-invasive technique for stimulating brain and neural tissue. The principle of magnetic stimulation is implicit in Faraday's law. The pulses of current are generated with a circuit containing a capacitor connected to the stimulating coil. With the capacitor charged to a certain level, the conducting state will cause the discharging of the capacitor through the coil. A magnetic field is generated proportional to this current. The rapid change in the magnetic field induces a current in conducting materials e.g. the body tissue. If the current induced in the human body is of sufficient amplitude and duration, it will excite neurons.

In the MagVita TMS therapy w/MagPro R20 TMS pulses are applied repetitively at a frequency of 10Hz. Such stimulation has been shown to be as effective as the predicate device in modulating cortical excitability. The observed and documented increase in cortical excitability after high frequency (10Hz) repetitive transcranial magnetic stimulation has been shown to persist beyond the duration of the train of stimulation. Repetitive Magnetic stimulation with the MagVita TMS therapy w/MagPro R20 is applied to the human brain on the left dorsolateral prefrontal cortex (DLPFC).

The MagVita TMS Therapy w/MagPro R20 is an integrated system consisting of the following components:

- MagPro Stimulator and Trolley
  - MagPro R20
  - Trolley with holding arrangements
- Coils for MT determination and Depression Treatment
  - Coil MCF-B65
- Marking apparatus for locating treatment area
  - Marking plate for Coil MCF-B65
  - Pen for marking, Cap, Ruler
- Patient head fixation
  - Treatment Chair
  - Vacuum Pump and Vacuum pillow
  - Super Flexible Arm mounted on the trolley
- Isolation Transformer

Intended Use/Indication for Use:

Treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.

Standards:
The MagVita TMS Therapy w/MagPro R20 has been tested and complies with the following standards

- ISO13485:2012
- IEC60601-1
- IEC60601-1-2

Non-Clinical performance data:

The non-clinical performance testing of the components of the MagVita TMS Therapy w/MagPro R20 has been tested as required, and cleared by the FDA earlier in:
K160280: MagPro R20
K150641: Chair, flexible arm, vacuum pump and pillow, isolation transformer, marking accessories and caps
K071821: Coil MCF-B65.

Substantial equivalence:

The MagVita TMS Therapy w/MagPro R20 is substantially equivalent to the predicate device (MagVita TMS Therapy System). The MagVita TMS Therapy w/MagPro R20 and the predicate device have identical intended use /indication for use, and the technological characteristics are very similar such that they in our view can be considered equivalent.

The MagVita TMS Therapy w/MagPro R20 and the predicate device are both indicated for

Treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.

Design of the MagVita TMS Therapy w/MagPro R20 is similar to the predicate device as both systems apply Transcranial Magnetic Stimulation as repetitive pulse trains at 10Hz delivered as brief rapidly alternating magnetic fields to induce electrical currents over the prefrontal cortex. Also the magnetic field/pulses for both devices are identical.
Both the MagVita TMS Therapy w/MagPro R20 and the predicate device have the same components consisting of TMS stimulator with software, electromagnetic coil and an articulated arm for positioning of the treatment coil. The operational procedures including system setup, patient preparations, motor threshold determination, coil positioning and treatment with predefined treatment stimulation parameters are essentially the same.

Characteristics of the Device as Compared to Predicate Device*

Area	MagVita TMS Therapy w/MagPro R20	MagVita TMS Therapy System (K150641)
Performance	Waveforms: Biphasic Frequency: 0.1 -20 pulses per second. Preset range of % MT: 50%-140%	Waveforms: Biphasic. Frequency: 0.1 -30 pulses per second or 0.1 -100 pulses per second, depending on model Preset range of % MT: 0% -140%
	Recommended standard treatment: Stimulation Intensity: 120% MT (MT=Motor Threshold intensity) Repetition rate: 10 Hz Train duration: 4 sec Interval between pulses: 26 sec Numbers of pulses/session: 3000	Recommended standard treatment: Stimulation Intensity: 120% MT (MT=Motor Threshold intensity) Repetition rate:10 Hz Train duration: 4 sec Interval between pulses: 26 sec Numbers of pulses/ session: 3000
	Output Stimulation Parameters: Available Stimulation Amplitude in Standard Motor Threshold (SMT) units Amplitude Range: 0 - 1.2 SMT Pulse width: 290 µs (±5%), Biphasic sinusoid waveform. Frequency Range: 0.1-20 pps (±2%)	Output Stimulation Parameters: Available Stimulation Amplitude in Standard Motor Threshold (SMT) units Amplitude Range: 0 - 1.7 SMT Pulse width: 290 µs (±5%), Biphasic sinusoid waveform. Frequency Range: 0.1-30 pps (±2%) or 0.1-100 pps, depending on model
Coil Configuration Cooling	Figure-of-eight coil Air core Liquid cooling	Figure-of-eight coil Air core Forced liquid cooling
Standards met	Company complies with ISO 13485:2012	Company complies with ISO 13485:2012.
Electrical safety	Complies with IEC60601-1 and IEC60601-1-2.	Complies with IEC60601-1, IEC60601-1-1 and IEC60601-1-2.

*For a more comprehensive comparison of devices please refer to section 12 Substantial Equivalence Comparison

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Conclusion:

The above summary of the comparison, demonstrates and supports the substantial equivalency of the *MagVita TMS Therapy w/MagPro R20* to the MagVita *TMS Therapy System.*

The indication for use, the target population, the dosage, the treatment procedure, the treatment position and all relevant protocol parameters (intensity, repetition rate, number of pulses in a train, numbers of trains, number of treatment sessions) are identical for the *MagVita TMS Therapy w/MagPro R20* and the predicate device *MagVita TMS Therapy System*.

The transducer design (figure-of-eight) are equivalent and the realized magnetic properties of the coils used in the *MagVita TMS Therapy w/MagPro R20* and the predicate system are substantial equivalent for the two coils.

The reliability of the positioning method used by the *MagVita TMS Therapy w/MagPro R20* is, based on the direct relationship of the underlying cortical brain anatomy to the patient's scalp, as is the method used in the predicate device. The method for identifying the correct treatment position in the MagVita TMS Therapy w/MagPro R20 is as effective as the method employed by the predicate device, as they are identical.

The *MagVita TMS Therapy w/MagPro R20* does not introduce any new safety considerations in comparison to the predicate device.

All other identified differences between the two systems are minor and without any known impact on safety or efficacy.

EXHIBIT E

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 16, 2016

Tonica Elektronik A/S
Lise Terkelsen
QA/RA Manager
Lucernemarken 15
DK-3520 Farum, Denmark

Re: K160280
Trade/Device Name: MagPro R20
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked Response Electrical Stimulator
Regulatory Class: Class II
Product Code: GWF
Dated: February 1, 2016
Received: February 2, 2016

Dear Lise Terkelsen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

William J. Heetderks -A

Digitally signed by William J. Heetderks -A
DN: c=US, o=U.S. Government, ou=HHS, ou=NIH, ou=People, 0.9.2342.19200300.100.1.1=0010149848, cn=William J. Heetderks -A
Date: 2016.05.16 16:55:59 -04'00'

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160280

Device Name
MagPro R20

Indications for Use *(Describe)*
MagPro R20 is intended to be used for stimulation of peripheral nerves for diagnostic purposes.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Submitter's Information

Name of 510(k) owner:	Tonica Elektronik A/S Lucernemarken 15 DK-3520 Farum, Denmark
Phone:	+45 4499 8444
Fax:	+45 4499 1544
Contact person:	Lise Terkelsen
Preparation date:	May 13th, 2016
Trade name:	MagPro R20
Common name:	MagPro R20
Classification name:	Evoked Response Electrical Stimulator
Classification:	Class II Medical Device
Product Code:	GWF
Regulation number:	21 CFR 882.1870
Identification of predicate device:	MagPro R30, K061645

Device description
MagPro R20 is a Magnetic stimulator used for Magnetic stimulation.
Magnetic stimulation is a non-invasive technique for stimulating neural tissue.
Application areas of magnetic stimulation are a sub-set of the application areas for current stimulation.

The MagPro R20 is connected to a Magnetic Coil which transfers the magnetic stimulation to the tissue.

The MagPro R20 consists of power electronics to generate the magnetic field in the Magnetic Coil. The MagPro R20 is controlled via a user interface, enabling the operator to overview all functions, stimulus sequences, controls, status and measured data. The MagPro R20 has a built-in computer and 2 small displays.
The magnetic pulse is Biphasic waveform and the stimulator can stimulate with a frequency of up to 20 pulses per second (pps).

Intended Use:
The MagPro R20 is intended for stimulation of peripheral nerves for diagnostic purposes.

Substantial Equivalence:
The MagPro R20 in this submission has the same characteristics as the predicate device, MagPro R30 (K061645). Stimulation of peripheral nerves is the intended application which applies to both devices.

They consist of a unit comprising power electronic to generate the magnetic fields in a Magnetic Coil. All includes a user interface to control the device via knobs and a display on the front panel.

The waveforms for the MagPro R20 and the MagPro R30 are biphasic. The maximum stimuli frequency is 30 pulses per second for MagPro R30 while 20 pulses per second for MagPro R20.

The MagPro R20 is CE-marked and complies with the Medical Device Directive 93/42/EEC. The MagPro R20 is developed and manufactured according to EN13485, “Medical devices – Quality management systems – Requirement for regulatory purposes”.

Area	New Device ***MagPro R20*** **Tonica Elektronik A/S**	Predicate Device ***MagPro R30*** **Tonica Elektronik A/S**	Conclusion
Indications for use	Is intended to be used for stimulation of peripheral nerves for diagnostic purposes.	Is intended to be used for stimulation of peripheral nerves for diagnostic purposes.	Identical
Energy used	Power Supply via Isolation Transformer Power Supply: 120V~, 50/60 Hz. Power consumption: Maximum 800VA	Power Supply via Isolation Transformer Power Supply: 120V~, 50/60Hz Power consumption: Maximum 2300VA	Identical Lower power consumption
Mechanical data	Dimensions (HxWxD): 150 x 390 x 440mm Weight: 20 kg / 44 lbs	Dimensions (HxWxD): 210 x 530 x 400mm Weight: 36kg / 79 lbs	R30 bigger and heavier than R20.
Pulse width	280 µsec Biphasic	280 µsec Biphasic	Identical
Console	MagPro R20 consists of a power module, a processor module and built in displays. The optional trolley supports the R20 and makes it moveable. The complete system is powered from an Isolation Transformer.	MagPro R30 consists of a power module, a processor module and a built in display. The optional trolley supports the R30 and makes it moveable. The complete system is powered from an Isolation Transformer.	Identical

User Interface	MagPro R20 has 2 displays
	• Intensity display
	  ◦ Coil temperature
	  ◦ Intensity
	• Menu display and indicators can show
	  ◦ Repetition rate
	  ◦ Pulses in train
	  ◦ Number of trains
	  ◦ Inter train interval
	  ◦ Start delay
	  ◦ Volume
		MagPro R30 has 1 display
		All parameter settings can be shown on the display.
		• Intensity
		• Repetition rate
		• Pulses in train
		• Number of trains
		• Inter train interval
		• Start delay
		• Amplitude
		• Realized di/dt
			Primary readout equivalent.
			
			MagPro R30 has a more complex interface. MagPro R20 is meant for everyday diagnostic purposes
			Same level of safety.

Area	New Device ***MagPro R20*** **Tonica Elektronik A/S**	Predicate Device ***MagPro R30*** **Tonica Elektronik A/S**	Conclusion
	• Status: enable/disable • Coil type	• Status: enable/disable • Coil temperature • Coil type • Available stimuli • Event log information and date/time • Treatment sequence can be stored and reused. Event log and Amplitude log can be exported. • Continuously readout of di/dt controlling the stability of the produced magnetic stimulation	

Testing

The MagPro R20 complies with the standard for electrical safety standard, IEC 60601-1 v3.1, and has been tested at a certified test center, UL Demko. EMC testing has been performed for compliance with the EMC standard, IEC 60601-1-2.

List of latest test reports:

Electrical Safety reports Tests performed by: UL International Demko A/S www.ul-europe.com		Electromagnetic Compatibility Reports Tests performed by: Delta (Danish Electronics, Light & Acoustics) www.delta.dk	
Test report no.	Test report name	Test report no.	Test report name
E360406-D1-CB	UL IEC 60601-1 Medical electrical equipment ANSI/AAMI ES60601-1:2005/A2:2010	T206073-1 DANAK-19/13416 Rev. A	DELTA Test Report: EMC test of MagPro R20
DK-38637-UL	CB certificate		

TABLE 1

Conclusion:

The MagPro R20 has the same intended use as the predicate device and the same technological features. The MagPro R20 does not raise new issues of safety and effectiveness and is substantially equivalent to the predicate device.

EXHIBIT F

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 31, 2015

Tonica Elektronik A/S
Lise Terkelsen
Regulatory Affairs/ Quality Assurance Specialist
Lucernemarken 15
DK-3520 Farum, Denmark

Re: K150641
Trade/Device Name: MagVita TMS Therapy System
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive Transcranial Magnetic Stimulation System
Regulatory Class: Class II
Product Code: OBP
Dated: March 10, 2015
Received: March 13, 2015

Dear Lise Terkelsen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150641

Device Name
MagVita TMS Therapy System

Indications for Use *(Describe)*
The MagVita TMS Therapy System is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k)

MagVita TMS Therapy System

510(k) Summary

Submitter's Information

Name of 510(k) owner:	Tonica Elektronik A/S Lucernemarken 15 DK-3520 Farum, Denmark
Phone:	+45 4499 8444
Fax:	+45 4499 1544
Contact person:	Lise Terkelsen Email: lise.terkelsen@tonica.dk

Preparation date:	July 24, 2015
Trade name:	MagVita TMS Therapy System
Common name:	Transcranial Magnetic Stimulator
Classification name:	Repetitive Transcranial Magnetic Stimulator for treatment of Major Depressive Disorder [21 CFR 882.5805, Product Code OBP]
Classification:	Class II Medical Device
Predicate Device:	NeuroStar TMS Therapy Systems (K083538, K133408) 21 CFR 882.5805, Repetitive Transcranial Magnetic Stimulation Product code: OBP Device Class: II

510(k)

MagVita TMS Therapy System

Device description

The MagVita TMS Therapy System is a computerized, electromechanical medical device that produces and delivers non-invasive, magnetic fields to induce electrical currents directed at regions of the cerebral cortex. The MagVita TMS Therapy System is indicated for

Treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode

Transcranial magnetic stimulation (TMS) is a non-invasive technique for stimulating brain and neural tissue. The principle of magnetic stimulation is implicit in Faraday's law. The pulses of current are generated with a circuit containing a capacitor connected to the stimulating coil. With the capacitor charged to a certain level, the conducting state will cause the discharging of the capacitor through the coil. A magnetic field is generated proportional to this current. The rapid change in the magnetic field induces a current in conducting materials e.g. the body tissue. If the current induced in the human body is of sufficient amplitude and duration, it will excite neurons.

In the MagVita TMS therapy system TMS pulses are applied repetitively at a frequency of 10Hz. Such stimulation has been shown to be as effective as the predicate device in modulating cortical excitability. The observed and documented increase in cortical excitability after high frequency (10Hz) repetitive transcranial magnetic stimulation has been shown to persist beyond the duration of the train of stimulation. Repetitive Magnetic stimulation with the MagVita TMS therapy system is applied to the human brain on the left dorsolateral prefrontal cortex (DLPFC).

The MagVita TMS Therapy System is an integrated system consisting of the following components:

- MagPro Stimulator and Trolley
  - MagPro family
  - Trolley with holding arrangements
- Coil for MT determination
  - Coil C-B60
- Marking apparatus for locating treatment area
  - Marking plate for Coil C-B60
  - Pen for marking, Cap, Ruler
- Patient head fixation
  - Treatment Chair
  - Vacuum Pump and Vacuum pillow
  - Super Flexible Arm mounted on the trolley
- Coil for Depression Treatment
  - Coil Cool-B65 with Coil Cooler unit
- Isolation Transformer

MagVita TMS Therapy System

Intended Use/Indication for Use:

Treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.

Standards:
The MagVita TMS Therapy System has been tested and complies with the following standards

- ISO 13485:2012
- IEC60601-1
- IEC60601-1-1
- IEC60601-1-2

Non-Clinical performance data:

The non-clinical performance testing of the components of the MagVita TMS Therapy System has been tested as required, and cleared by the FDA earlier on K061645, K071821 and K091940.

These tests along with the supportive clinical information from the predicate device demonstrate that the MagVita TMS Therapy System is as safe and effective as the predicate device for use in treatment of Major Depressive Disorder.

Substantial equivalence:

The MagVita TMS Therapy System is substantially equivalent to the predicate device (Neurostar TMS Therapy® System). The MagVita TMS Therapy System and the predicate device have identical intended use /indication for use, and the technological characteristics are very similar such that they in our view can be considered equivalent.

The MagVita TMS Therapy System and the predicate device are both indicated for

Treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.

Design of the MagVita TMS Therapy System is similar to the predicate device as both systems apply Transcranial Magnetic Stimulation as repetitive pulse trains at 10Hz delivered as brief rapidly alternating magnetic fields to induce electrical currents over the prefrontal cortex.
Both the MagVita TMS Therapy System and the predicate device have the same components consisting of TMS stimulator with software, electromagnetic coil and an articulated arm for positioning of the treatment coil. The operational procedures including system setup, patient preparations, motor threshold determination, coil positioning and treatment with predefined treatment stimulation parameters are essentially the same.

Characteristics of the Device as Compared to Predicate Device*

Area	MagVita TMS Therapy System	NeuroStar TMS Therapy System Neuronetics Inc. (K083538,K133408)
Performance	Waveforms: Biphasic. Frequency: 0.1 -30 pulses per second or 0.1 -100 pulses, depending on model Preset range of % MT: 0% -140%	Waveforms: Biphasic Frequency: 0.1 -30 pulses per second. Preset range of % MT: 80% -140%
	Recommended standard treatment: Stimulation Intensity: 120% MT (MT=Motor Threshold intensity) Repetition rate:10 Hz Train duration: 4 sec Interval between pulses: 26 sec Numbers of pulses/ session: 3000	Recommended standard treatment: Stimulation Intensity: 120% MT (MT=Motor Threshold intensity) Repetition rate: 10 Hz Train duration: 4 sec Interval between pulses: 26 sec Numbers of pulses/session: 3000
	Output Stimulation Parameters: Available Stimulation Amplitude in Standard Motor Threshold (SMT) units Amplitude Range: 0 - 1.7 SMT Pulse width: 290 µs (±5%), Biphasic sinusoid waveform. Frequency Range: 0.1-30 pps (±2%) or 0.1-100 pps, depending on model	Output Stimulation Parameters: Available Stimulation Amplitude in Standard Motor Threshold (SMT) units Amplitude Range: 0.22 - 1.6 SMT Pulse width: 185 µs (±10%), Biphasic sinusoid waveform. Frequency Range: 0.1-30 pps (±2%)
Coil Configuration Cooling	Figure-of-eight coil Air core Liquid cooling	Figure-of-eight coil Ferromagnetic core Ferrofluidic cooling
Standards met	Company complies with ISO 13485:2012.	Company complies with ISO 13485:2003
Electrical safety	Complies with IEC60601-1, IEC60601-1-1 and IEC60601-1-2.	Complies with UL60601-1 and UL60601-1-2

*For a more comprehensive comparison of devices please refer to section 12 Substantial Equivalence Comparison

Conclusion:

The above comparison, demonstrates and supports the substantial equivalency of the *MagVita TMS Therapy System* to the *NeuroStar TMS Therapy System*

The indication for use, the target population, the dosage, the treatment procedure, the treatment position and all relevant protocol parameters (intensity, repetition rate, number of pulses in a train, numbers of trains, number of treatment sessions) are identical for the *MagVita TMS Therapy System* and the predicate device *NeuroStar TMS Therapy System*.

The transducer design (figure-of-eight) are equivalent and the realized magnetic properties of the *MagVita TMS Therapy System* and the predicate device are substantial equivalent for the two coils.

The reliability of the positioning method used by the *MagVita TMS Therapy System* is, based on the direct relationship of the underlying cortical brain anatomy to the patient's scalp, as is the method used in the predicate device. The method for identifying the correct treatment position in the MagVita TMS Therapy System is at least as effective as the method employed by the predicate device.

The *MagVita TMS Therapy System* does not introduce any new safety considerations in comparison to the predicate device.

All other identified differences between the two systems are minor and without any known impact on safety or efficacy.

EXHIBIT G

K091940

510(k)

MagPro R30 incl. MagOption, X100, X100 incl. MagOption

510(k) Summary

MAR 2 6 2010

Name of 510(k) owner:	Tonica Elektronik A/S Lucernemarken 15 DK-3520 Farum Denmark
Phone: Fax:	+45 4499 8444 +45 4499 1544
Contact:	Lise Terkelsen
Preparation date:	June 19, 2009
Trade name:	MagPro R30 incl. MagOption MagPro X100 MagPro X100 incl. MagOption
Common name:	MagPro R30 incl. MagOption MagPro X100 MagPro X100 incl. MagOption
Classification name:	Evoked Response Electrical Stimulator
Identification of predicate devices:	MagPro R30, K061645 MagPro, K926516 Magstim Super Rapid², K051864 Keypoint (K944547) Digitimer DS7A (K051357)

K091940

510(k)

MagPro R30 incl. MagOption, X100, X100 incl. MagOption

Device description

MagPro R30 incl. MagOption, MagPro X100 and MagPro X100 incl. MagOption are Magnetic stimulators used for Magnetic stimulation. These three devices are, together with the predicate device MagPro R30, called "MagPro Family". Hereafter we name the three devices in this submission "the new devices".

Magnetic stimulation is a non-invasive technique for stimulating neural tissue. Application areas of magnetic stimulation are a sub-set of the application areas for current stimulation.

The new devices are connected to a Magnetic Coil which transfers the magnetic stimulation to the tissue. All Standard coils as well as the Fluid and Cool coils can be used with the MagPro devices, (K926516, K061645, K071821).

The new devices are magnetic stimulators, featuring Biphasic, Monophasic, Halfsine, Biphasic Burst waveform, stimulation rates up to 100 pulses per second (pps), stimulus sequences and protocols controlled via a built-in computer and 8,4" display.

Intended Use:

The magnetic stimulators are intended to be used for stimulation of peripheral nerves for diagnostic purposes.

Substantial Equivalence:

The new devices in this submission have the same characteristics as the predicate devices, MagPro R30 (K061645), MagPro (K926516) and Magstim Super Rapid² (K051864). Stimulation of peripheral nerves is the intended application which applies for all these magnetic stimulator devices.

They consist of a unit comprising power electronic to generate the magnetic fields in a Magnetic Coil. All includes a user interface to control the device via knobs or touch screen and a display on the front panel.

The difference in performance between the new devices and the predicate devices are thoroughly compared and discussed in the "Substantial Equivalence" section. Evidence for the higher repetition rate of 100pps is documented and found substantial equivalent to current stimulators, Keypoint (K944547) and Digitimer DS7A (K051357), which are able to perform at more powerful repetition rates.

The new devices are CE-marked and comply with the Medical Device Directive 93/42/EEC and also the Canadian CMDR. The new devices are developed and manufactured according to EN13485, "Medical devices – Quality management systems – Requirement for regulatory purposes". The new devices comply with the standard for electrical safety standard, IEC 60601-1, and have been tested at a certified test center, UL Demko. EMC testing has been performed for compliance with the EMC standard, IEC 60601-1-2. The MagPro devices fulfill the requirements in the standard IEC 60601-1-6 Usability.

K091940

510(k)

MagPro R30 incl. MagOption, X100, X100 incl. MagOption

Conclusion:
The MagPro R30 incl. MagOption, MagPro X100 and MagPro X100 incl. MagOption have the same intended use as the predicate magnetic stimulator devices and the same technological features. The difference in performance is shown equivalent to various predicate devices.

The new devices do not raise new issues of safety and effectiveness and are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Tonica Elektronik A/S
c/o Ms. Lise Terkelsen
Lucernemarken 15
DK-3520 Farum
Denmark

MAR 2 6 2010

Re: K091940
Trade/Device Name: MagPro R30 with Magoption, MagPro X100, and MagPro X100 with MagOption
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked Response Electrical Stimulator
Regulatory Class: Class II
Product Code: GWF
Dated: March 15, 2010
Received: March 18, 2010

Dear Ms. Terkelsen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) number: K091940

Div/Branch	Last Name	Date	Div/Branch	Last Name	Date
DONEDINNOB	HUTTER	25MAR10			

For Office of Compliance Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=318

For Office of Surveillance and Biometrics Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=423

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table
1/11/10	Diane Garcia	Liability/Warranty sentence added at bottom of 1st page

Drafted: Joseph Hutter, Ph.D.
Edited:
Final:
Typed: Marisol Lendor, March 25, 2010

510(k)

MagPro R30 incl. MagOption, X100, X100 incl. MagOption

Indications for Use

510(k) Number (if known):

Device Name:	MagPro R30 with MagOption MagPro X100 MagPro X100 with MagOption
Indications for Use:	The devices are intended to be used for stimulation of peripheral nerves for diagnostic purposes.

Prescription Use ___X___ and/or Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

JOE HUTTER

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K091940

EXHIBIT H

510(k) Summary

OCT 3 1 2006

Name of 510(k) owner:	Tonica Elektronik A/S Lucernemarken 15 DK-3520 Farum Denmark
Phone:	+45 4499 8444
Fax:	+45 4499 1544
Contact:	Lise Terkelsen
Preparation date:	August 31, 2006
Trade name:	MagPro R30
Common name:	MagPro R30
Classification name:	Evoked Response Electrical Stimulator
Identification of predicate devices:	MagPro, K926516 Magstim Super Rapid², K051864

Device description
MagPro R30 is a Magnetic stimulator used for Magnetic stimulation.
Magnetic stimulation is a non-invasive technique for stimulating neural tissue.
Application areas of magnetic stimulation are a sub-set of the application areas for current stimulation.

The MagPro R30 is connected to a Magnetic Coil which transfers the magnetic stimulation to the tissue. The original coils MC-125 and MC-B70 in K926516 can be used with the MagPro R30 as well as the coils C-100, C-B60 and MMC-140-II.

The MagPro R30 consists of power electronics to generate the magnetic field in the Magnetic Coil. The MagPro R30 is controlled via a simple user interface, enabling the operator to overview all functions, stimulus sequences, controls, status and measured data. The MagPro R30 has a built-in computer and a 8.4" display.
The magnetic pulse is Biphasic waveform and the stimulator can stimulate with a frequency of up to 30 pulses per second (pps).

Intended Use:
The MagPro R30 is intended to be used for stimulation of peripheral nerves for diagnostic purposes.

Substantial Equivalence:
The MagPro R30 in this submission has the same characteristics as the predicate devices, MagPro (K926516) and Magstim Super Rapid² (K051864). Stimulation of peripheral nerves is the intended application which applies for all three devices.

They consist of a unit comprising power electronic to generate the magnetic fields in a Magnetic Coil. All includes a user interface to control the device via knobs and a display on the front panel.

The waveforms for the MagPro R30 and the Magstim Super Rapid² are biphasic, for the MagPro the waveforms are biphasic and monophasic. The Max. stim. frequency is 30 pulses per second for MagPro R30 and Magpro, while for the Magstim Super Rapid² the frequency is 60 pulses per second.

The realized magnetic field the stimulator is produced together with the connected coil, is comparable to the old MagPro in K926516. The mechanical, electrical and magnetic parameters of the coils in this submission are very near to the parameters of the predicate coils. All coils are based on the same technology, design and material used.

The MagPro R30 is CE-marked and complies with the Medical Device Directive 93/42/EEC. The MagPro R30 is developed and manufactured according to EN13485, "Medical devices – Quality management systems – Requirement for regulatory purposes". The MagPro R30 complies with the standard for electrical safety standard, IEC 60601-1, and has been tested at a certified test center, UL Demko. EMC testing has been performed for compliance with the EMC standard, IEC 60601-1-2.

Conclusion:
The MagPro R30 has the same intended use as the predicate devices and the same technological features.

All coils are a variant to the original approved in K926516.

The clinical performance of the magnetic field to the patient is unchanged from the predicate coils to the proposed coils.

The MagPro R30 and coils do not raise new issues of safety and effectiveness and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Lise Terkelsen
Tonica Elektronik A/S
Lucernemarken 15
DK-3520 Farum
Denmark

OCT 3 1 2006

Re: K061645
Trade/Device Name: MagPro R30 Magnetic Stimulator used with Model MC-125, MC-B70, C-100, C-B60, and MMC-140-II Coils
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked response electrical stimulator
Regulatory Class: Class II
Product Code: GWF
Dated: September 19, 2006
Received: September 22, 2006

Dear Ms. Terkelsen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration

and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):	K061645
Device Name:	MagPro R30
Indications for Use:	The device is intended to be used for stimulation of peripheral nerves for diagnostic purposes.

Prescription Use ___X___ Over-The-Counter Use _____

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061645